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Trimedyne®

SEP - 8 2004

Trimedyne® Holmium Laser System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Submitter Information:

Trimedyne, Inc.
15091 Bake Parkway
Irvine, CA 92618
949-951-3800

Contact Person: Glenn Yeik
President and COO

Summary Date: 20 August 2004

II. Device Name

Proprietary: Trimedyne Holmium Laser System, including:

- OmniPulse™ Holmium Laser System (Model 1210)
- OmniPulse MAX™ Holmium Laser System (Model 1210-VHP)
- OmniPulse Jr.™ Holmium Laser System (Model 1230-30)
- Model 1500-A Holmium Laser System

Common: Holmium:Yttrium Aluminum Garnet (Holmium:YAG) Laser

Classification: Laser-Powered Instrument

III. Predicate Device

Trimedyne Holmium Laser System

IV. Device Description

The Trimedyne Holmium Laser System is a medical grade, Class IV, pulsed, solid state Holmium:YAG laser system designed to deliver pulsed infrared laser energy with a wavelength of 2.1 μm and 350 microseconds pulsewidth. Menu-driven control options allow the users to select pulse repetition rate, output energy, and lasing duration.

V. Intended Use

The Trimedyne Holmium:YAG Laser System is indicated for superficial incision, excision, resection, ablation, coagulation, hemostasis, and vaporization, with or without an endoscope, in multispecialty applications.

When used in conjunction with the Trimedyne Side Firing Needle with Vent Sheath family of optical fiber delivery devices, these laser systems may be used for interstitial incision, excision, resection, ablation, coagulation, hemostasis, and vaporization in multispecialty applications.

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VI. Technological Characteristics

The laser system is a Holmium:YAG laser that emits light at a wavelength of 2.1 μm (near infrared) and a pulsewidth of 350 microseconds. The laser has the capability of attaining a maximum output of 100 watts of power.

VII. Nonclinical Data

No non-clinical data were submitted in this Premarket Notification.

VIII. Clinical Data

No clinical tests were submitted in this Premarket Notification.

IX. Conclusion

The Trimedyne Holmium:YAG Laser System is substantially equivalent to the predicate device described in this Premarket Notification. Therefore, upon clearance of this submission, the Trimedyne Holmium:YAG Laser System will be marketed with the proposed modified/clarified indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Trimedyne, Inc.
c/o Ms. Laura Danielson
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, Minnesota 55112-1891

Re: K041660
Trade/Device Name: Trimedyne Holmium Laser System, including:
OmniPulse™ Holmium Laser System (Model 1210)
OmniPulse MAX™ Holmium Laser System (Model 1210-VHP)
OmniPulse Jr.™ Holmium Laser System (Model 1230-30)
Model 1500-A Holmium Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 23, 2004
Received: August 24, 2004

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

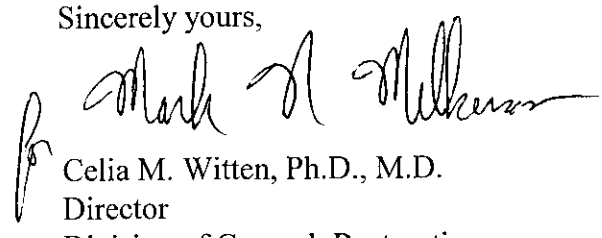
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K041660

Device Name: Trimedyne Holmium Laser System, including:

- OmniPulse™ Holmium Laser System, Model 1210
- OmniPulse MAX™ Holmium Laser System, Model 1210-VHP
- OmniPulse Jr.™ Holmium Laser System, Model 1230-30
- Model 1500-A Holmium Laser System

Indications for Use:

Superficial incision, excision, resection, ablation, coagulation, hemostasis, and vaporization, with or without an endoscope, in the following indications:

1. Dermatology and Plastic Surgery of soft, mucosal, fatty, and cartilaginous tissues, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including:

- scars
- tattoo removal
- vascular lesions (including port wine stains, hemangioma, telangiectasia [facial, leg], and rosacea)
- corns
- papillomas
- basal cell carcinomas
- lesions of skin and subcutaneous tissue
- plantar warts
- periungual and subungual warts
- debridement of decubitus ulcer
- skin tag vaporization

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041660

Indications - continued

2. Gastroenterological/Gastrointestinal Surgery, including:

- cholecystectomy
- lysis of adhesions
- appendectomy
- biopsy
- pylorostenotomy
- benign and malignant lesions
- rectal polyps of sigmoid colon
- gall bladder calculi
- biliary/bile duct calculi
- benign and malignant neoplasm
- polyps
- colitis
- ulcers
- angiodysplasia
- hemorrhoids
- varices
- esophagitis
- esophageal ulcer
- Mallory-Weiss tear
- gastric ulcer
- duodenal ulcer
- non-bleeding ulcer
- gastric erosions
- colorectal cancer
- gastritis
- bleeding tumors
- pancreatitis
- vascular malformations
- telangiectasias
- telangiectasias of the Osler-Weber-Rendu disease

3. General Surgery of soft tissue, including:

- skin incision
- tissue dissection
- excision of external tumors and lesions
- complete or partial resection of internal organs
- tumors and lesions
- tissue ablation
- mastectomy
- hepatectomy
- pancreatectomy
- splenectomy
- thyroidectomy
- parathyroidectomy
- hemiorrhaphy
- tonsillectomy
- lymphadenectomy
- partial nephrectomy
- pilonidal cystectomy
- resection of lipoma
- pelvic adhesiolysis
- debridement of decubitus ulcer
- hemorrhoids
- pilodidal cyst removal and repair
- debridement of statis ulcer
- biopsy

4. Genitourinary Surgery/Urology, including:

- superficial urinary bladder tumors
- invasive bladder carcinoma
- urethral strictures
- lesions of the external genitalia
- bladder
- urethral and ureteral tumors
- condylomas
- urethral and penile hemangioma
- bladder neck obstructions
- holmium laser incision, excision, resection, ablation, hemostasis, vaporization, and enucleation in the treatment of benign prostatic hyperplasia (BPH)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K041660

Indications - continued

5. Gynecological Surgery during open and endoscopic procedures, including:

- condyloma acuminata

6. Lithotripsy and Percutaneous Urinary Lithotripsy, including:

- fragmentation of urinary calculi
- fragmentation of urethral calculi
- fragmentation of kidney calculi
- treatment of distal impacted fragment of steinstrasse when guide wires cannot be passed

7. Orthopedic Surgery in pathological soft and cartilaginous tissue in small and large joints, including:

- knee meniscectomy
- knee synovectomy
- chondromalacia and tears
- loose body debridement
- lateral retinacular release
- debridement of the degenerative knee
- plica removal
- ligament and tendon release
- contouring and sculpting of articular surfaces
- debridement of inflamed synovial tissue
- capsulectomy in the knee
- chondroplasty in the knee
- chondromalacia ablation

8. Otorhinolaryngology (ENT) Surgery in soft, mucosal, cartilaginous and bony tissue, including:

- endosinus surgery
- functional endoscopic sinus surgery
- turbinate procedures (e.g.. turbinectomy)
- dacryocystorhinostomy (DCR)
- ethmoidectomy
- polypectomy
- maxillary antrostomy
- frontal sinusotomy
- sphenoidotomy

Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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Indications - continued

9. Percutaneous Cervical, Lumbar, and Thoracic Disc Decompression / Discectomy: Superficial incision, excision, resection, ablation, coagulation, hemostasis and vaporization, with or without an endoscope, in the following:

- Percutaneous Lumbar Disc Decompression/Discectomy in soft, cartilaginous, and bony tissue, including:
  - foraminoplasty
- Percutaneous Cervical Disc Decompression/Discectomy in soft tissue, in patients with:
  - uncomplicated ruptured or herniated discs
  - neck pain with radiation down the arm
  - symptoms and signs of sensory loss, tingling, numbness, muscle weakness, and/or decreased deep tendon reflexes
  - MRI, CT, myelogram, or discogram findings of disc herniation consistent with patient signs and symptoms
  - positive electromyography and/or nerve conduction studies
  - no improvement after 12 weeks of conservative therapy (i.e., physical therapy, traction, bed rest, exercises, and medication)
- Percutaneous Thoracic Disc Decompression/Discectomy in soft tissue, in patients with:
  - uncomplicated ruptured or herniated discs
  - thoracic and intercostal intractable pain
  - paresthesias at levels appropriate to the herniated discs visualized on MRI and CT-myelography
  - MRI, CT, myelogram, or discogram findings of disc herniation consistent with patient signs and symptoms
  - no improvement after 12 weeks of conservative therapy (i.e., physical therapy, traction, bed rest, exercises, and medication)

Interstitial incision, excision, resection, ablation, coagulation, hemostasis, and vaporization in multispecialty applications; interstitial applications should only be performed using the Trimedyne Side Firing Needle with Vent Sheath family of optical fiber delivery devices.

Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041660